IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BOARD OF PATENT APPEALS AND INTERFERENCES

REPLY BRIEF FOR THE APPELLANT

In re Application of Avi J. Ashkenazi Serial No.: 09/894,924 Filed: 06/28/2001 For: DcR3 polypeptide, a TNFR homolog	Group Art Unit: 1646 Examiner: C. Kaufman

Mail Stop Appeal Brief – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir,

The following information and arguments are provided pursuant to 37 C.F.R. § 1.193(b).

(1) Statement of New Issues Raised in Examiner's Answer Warranting Reply Brief

The Examiner, in her Answer, has raised the following new issues warranting response by Appellant by this reply brief:

(a) The Examiner newly cites, but misstates and misapplies, the holding of the Federal Circuit in *Noelle v. Lederman*, 69 USPQ2d 1508 (Fed.Cir. 2004);

(b) The Examiner argues that *In re Wertheim and Mishkin*, 209 USPQ 554 (CCPA 1981) is inapplicable, under a *per se* rule, to applications that do not claim priority under 35 U.S.C. 119 or 120 to an earlier filed application; and

(c) The Examiner improperly equates the presumption of validity under 35 U.S.C. 282 with a substantive doctrine precluding evaluation of the actual teachings of a patent disclosure for prior art purposes under 35 U.S.C. 102(e).

(2) Arguments

(a) The Examiner has Misconstrued and Misapplied *Noelle v. Lederman*

In her Answer, the Examiner states that the recently decided case of *Noelle v. Lederman,* 69 USPQ2d 1508 (Fed. Cir 2004) mandates a conclusion that the disclosure of U.S. Patent No. 5,885,800 (*Emery et al.*) is sufficient to anticipate the present claims. In essence, the position of the Examiner is that the Federal Circuit held that disclosure of a "fully characterized antigen" establishes *per se* compliance with the written description requirement of 35 U.S.C. §112, first paragraph for an antibody to such antigen.

Initially, Appellant notes, that by her reliance on *Noelle v. Lederman*, the Examiner appears to accept the principle that the written description requirement of §112, first paragraph, must be established in order for a patent to anticipate a later claim to subject matter under 35 U.S.C. §102(e). This position is inconsistent with past positions of the Examiner holding that the sole requirement for a patent to anticipate under §102(e) a later claimed invention is whether the patent disclosure contains a teaching sufficient to *enable* a person of skill to make the invention claimed. It also compels a conclusion that the patent disclosure, as Appellants have argued, must meet all of the relevant statutory requirements – including §101 –in order for that prior art patent to be entitled to claim the subject matter at issue.

As to the substance of the argument, Appellant submits that *Noelle* neither stands for the proposition stated, nor that it, when applied to the present application, renders the *Emery et al.* publication sufficient to anticipate the present claims under 35 U.S.C. §102(e).

First, the court in *Noelle* acknowledges that assessing compliance with the written description requirement is a fact-intensive and case-specific exercise. In fact, the court explicitly stated that cases pertaining to 112, written description "must be decided on [their] own facts." *Id.* at 1513. Reading *Noelle* to hold that it establishes a fact-independent *per se* rule that any monoclonal antibody would be adequately described by a disclosure of a "sufficiently characterized" antigen would ignore the precedent that *Noelle* acknowledges exists, as well as more recent precedent of that court. *See, e.g., Chiron v. Genentech* 70 USPQ2d 1321 (Fed. Cir.

2004) (holding claim to monoclonal antibody not sufficiently described by priority application); see also, *Johns Hopkins University v. CellPro, Inc.*, 47 USPQ2d 1705 (Fed. Cir. 1998). One cannot simply impose a *per se* rule concerning sufficiency of disclosure for an entire class of molecules as the Examiner suggests.

Second, applying the same PTO guidelines that the court cites in *Noelle* properly compels a finding that the *Emery et al.*, disclosure does not sufficiently describe the claimed antibodies under 35 U.S.C. §112, first paragraph. As Appellant noted in its Appeal brief, the disclosure of *Emery et al.*, provides an insufficient description of the nucleic acids – and consequently of antibodies and other subject matter – that depend on use and exploitation of the properties of the nucleic acid. The Examiner does not appear to contest Appellant's scientific characterization of the *Emery et al*, disclosure.

Finally, even accepting the premise from *Noelle* that a "fully characterized antigen" provides a sufficient description of an antibody raised to it, Appellant submits that *Emery* et al., remains insufficient to anticipate the presently claimed antibodies. The inadequacies of the *Emery et al.*, disclosure make it clear that the antigen at issue here has not, in fact, been "fully characterized" by *Emery et al.* A simple review of the *Emery et al.*, disclosure shows that *Emery et al.*, never produced (i.e., expressed and isolated) the antigen (i.e., the polypeptide that would have to be used to raise the antigen). Nor did *Emery et al.*, characterize the antigen at issue here – such as by identifying with credible evidence particular biological or functional properties or the role of the polypeptide antigen. As such, Appellant submits that the *Emery et al.* disclosure did not "fully characterize" the antigen to which the presently claimed antibody binds, and as such, cannot anticipate this claim under §102(e).

(b) The Examiner Improperly Limits the Holding of *Wertheim*

The Examiner dismisses Appellant's arguments that *Wertheim* requires a patent disclosure to adequately describe and enable the claimed invention in a manner that fully complies with §112, first paragraph in order for that patent to anticipate under §102(e). The Examiner states that *Wertheim* is inapplicable in the present case, because the *Emery* patent does not claim priority under §120 to any earlier filed application. The Examiner also asserts that the *Wertheim* holding does not mandate compliance with §101.

The logic of *Wertheim*, based as it is on *Alexander Milburn Co. v. Davis-Bournonville Co.*, 270 U.S. 390, 401 (1926), mandates the opposite conclusion. In *Wertheim*, the court assessed the character of the disclosure in the priority application, compared it to the character of the disclosure of the application that led to the patent, and concluded that the difference rendered the earlier application insufficient to support under §112 the claims at issue. The essential holding of *Wertheim*, thus, is that an insufficient disclosure renders a patent incapable of anticipating under §102(e) subject matter claimed in a later application. The fact that the insufficient disclosure in the present case (i.e., in the *Emery et al* patent) is in the application that actually led to the patent does not cure its deficient teaching and render it compliant with §112, first paragraph, and thereby sufficient under §102(e) to anticipate subject matter it would not be entitled to claim.

The Examiner also errs by concluding that compliance with §101 is not required in order for a patent to meet the requirements of §112, first paragraph. As noted in appellant's appeal brief, it is well settled law that enablement requirement of §112, first paragraph, incorporates as a matter of law the requirements of §101. See, e.g., *In re Zeigler,* 26 USPQ2d 1600 (Fed Cir. 1993); *In re Brana,* 34 USPQ2d 1436 (Fed. Cir. 1995) and *In re Fouche,* 169 USPQ 429 (CCPA 1971).

(c) The Presumption of Validity under §282 Does Not Shield Unclaimed Subject Matter

The Examiner suggests that, in view of the presumption of validity that attaches to an issued U.S. patent, Appellant's may not contest that the *Emery et al.*, patent disclosure is insufficient to anticipate the presently claimed invention under §102(e). Appellant submits that §282 is wholly irrelevant to this inquiry. Initially, Appellant notes that the presumption of validity attaches to the *claims* of a patent, not to a patent's *disclosure* in general. *See, e.g., Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.,* 230 USPQ 416 (Fed. Cir. 1986), *cert. denied,* 484 U.S. 823 (1987); *Glaros v. H.H. Robertson Co.,* 230 USPQ 393 (Fed. Cir. 1986), *cert. dismissed,* 479 U.S. 1072 (1987) (both cases requiring a challenger to prove invalidity on a *claim-by-claim* basis). *Emery et al.*, does not contain a claim corresponding to the subject matter of the claims in the present application. Thus, the presumption of validity does not, in any way, preclude the Appellant from challenging the sufficiency of disclosure of the *Emery et al's* disclosure unrelated to the *claims* of the *Emery et al.* patent .

In any event, the Examiner cannot use the presumption of validity under §282 to argue that the disclosure of *Emery, et al.* is unassailable. The presumption of validity merely operates as a procedural device to specify whose burden it is to establish, by clear and convincing evidence, that an issued patent claim is invalid. *See, e.g., New England Braiding Co., Inc. v. A.W. Chesterton Co.*, 23 USPQ2d 1622, 1625 (Fed. Cir. 1992). Even assuming that the presumption of validity does arise with respect to *Emery et al,* Appellant has put forth sufficient evidence to prove that the *Emery et al,* disclosure is scientifically insufficient to satisfy § 112 requirements. As noted above, the Examiner does not contest Appellant's technical characterization of the *Emery et al*, disclosure in any way. As a result, Appellant submits that even if a higher standard is mandated by §282 with regard to the disclosure of an issued patent, that standard has been met in the present case.

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3. Conclusion

In view of the points made above, Appellant believes that the pending claims 14, 67, 69 to 72, 74 to 77 and 79 to 85 are in condition for allowance and should be passed to issue. Accordingly, Appellant respectfully requests the Board to reverse the rejections of record.

Please charge any necessary fees pursuant to 37 CFR §1.17(c) to deposit account No. 18-1260.

Respectfully submitted,
GENENTECH, INC.

Date: July 6, 2004 By: _____

Jeffrey P. Kushan
Reg. No. 43,401
Telephone No. (202) 736-8914

Appendix: Appealed Claims

14. (Twice Amended) An isolated antibody which binds to a DcR3 polypeptide, wherein said DcR3 polypeptide (a) comprises amino acids 1 to 300 of Fig. 1 (SEQ ID NO:1) or (b) comprises amino acids 1 to X, wherein X is any one of amino acids 215 to 300 of Fig. 1 (SEQ ID NO:1).

67. The antibody of claim 14 wherein said antibody is a monoclonal antibody.

69. The antibody of claim 67 wherein said antibody is a chimeric antibody.

70. The antibody of claim 67 wherein said antibody is a human antibody.

71. (Amended) The antibody of claim 14 wherein said antibody binds to a DcR3 polypeptide consisting of amino acids 1 to 300 of Fig. 1 (SEQ ID NO:1).

72. The antibody of claim 71 wherein said antibody is a monoclonal antibody.

74. The antibody of claim 72 wherein said antibody is a chimeric antibody.

75. The antibody of claim 72 wherein said antibody is a human antibody.

76. (Amended) The antibody of claim 14 wherein said antibody binds to a DcR3 polypeptide consisting of amino acids 1 to 215 of Fig. 1 (SEQ ID NO:1).

77. The antibody of claim 76 wherein said antibody is a monoclonal antibody.

79. The antibody of claim 77 wherein said antibody is a chimeric antibody.

80. The antibody of claim 77 wherein said antibody is a human antibody.

81. (Amended) An isolated monoclonal antibody which binds to a DcR3 polypeptide consisting of amino acids 1 to 300 of Fig. 1 (SEQ ID NO:1) or consisting of amino acids 1 to 215 of Fig. 1 (SEQ ID NO:1).

82. The antibody of claim 80 wherein said antibody is a chimeric antibody.

83. The antibody of claim 80 wherein said antibody is a human antibody.

84. The antibody of claim 80 wherein said antibody is expressed in a recombinant host cell selected from the group consisting of a CHO cell, yeast cell and *E. coli*.

85. The antibody of claim 80 wherein said antibody is linked to a detectable moiety selected from the group consisting of one or more radioisotopes, fluorescent compounds, chemiluminescent compounds, and enzymes.